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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/606,712 | 06/26/2003 | Stephen Dirk Pacetti | 50623.273 | 5771 |

7590 06/16/2006
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| EXAMINER |
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TADESSE, YEWEBDAR T

| ART UNIT | PAPER NUMBER |
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1734

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|--|--|
| Office Action Summary | Application No. 10/606,712 | Applicant(s) PACETTI, STEPHEN DIRK | |
| | Examiner Yewebdar T. Tadesse | Art Unit 1734 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>09/29/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I in the reply filed on 04/03/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 11-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/03/2006.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP2003-211063 in view of Kropfield (US 5,810,254).

As to claims 1 and 6, JP'063 discloses (see Fig 1) a coating apparatus capable of coating stent comprising a nozzle assembly having feed conduit (passage 10) capable of feeding polymer, in fluid communication with a source, a solvent feed conduit (8), in fluid communication with the solvent tank, that is not in fluid communication with the polymer feed conduit and dispenses the solvent, the solvent mixes with the polymer when the polymer and solvent are dispensed out from the nozzle assembly, and an atomizing air conduits (4), in communication with the compressed gas port (9), that is not in fluid communication with the polymer feed conduit and the solvent feed conduit and that uses compressed air from the atomizer to atomize the solvent and polymer that are dispensed out from the nozzle assembly. JP'063 lacks teaching lacks teaching a solvent pump that pumps a solvent from a solvent reservoir; a polymer pump that pumps a polymer from a polymer reservoir. Kropfield discloses a pump that pumps material A from a reservoir capable of holding a polymer and drug mixture; a second pump that pumps a second material (B capable of being solvent) from a second reservoir. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a solvent pump that pumps a solvent from a solvent reservoir; a polymer pump that pumps a polymer from a polymer reservoir in JP'063 to continuously supply materials to the coating nozzle as shown by Kropfield indicating the entire spraying assembly on Fig 1.

As to claim 4, in JP'063 (see Fig 1) the nozzle assembly enables external atomization of the solvent and polymer.

As to claim 5, in JP'063 (see Fig 1) the polymer feed conduit is positioned within feed conduit such that the solvent feed conduit such that the 'solvent feed conduit circumscribes the polymer.

Regarding claim 7, in JP'063 (see Fig 1) the solvent of the solvent reservoir is a better solvent for the polymer than for the drug.

As to claim 8, in JP'063 (see Fig 1) an outlet section of the atomizing air conduit is angled relative to the polymer and solvent feed conduits.

With respect to claim 9, in JP'063 (see Fig 1) the solvent or polymer feed conduit extends out from the atomizing air conduit.

As to claim 10, in JP'063 (see Fig 1) the polymer feed conduit is recessed with respect to the solvent feed conduit.

6. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leidner et al (US 6,056,993) or Jayaraman (US 2003/0099765) in view of Bhat et al (US 6,503,954), JP 2003-211063 and Kropfield (US 5,810,254).

As to claims 1-3, Leidner et al discloses (see Fig 1) a stent coating apparatus comprising a stent mandrel fixture capable of securely supporting a stent during a coating process, wherein the stent mandrel-fixture is further capable of rotating or translating the stent during a coating process. Jayaraman also discloses (see Figs 4 and 6; and paragraphs 9 and 25) a stent coating apparatus comprising a stent mandrel

fixture capable of securely supporting a stent during a coating process, wherein the stent mandrel-fixture is further capable of rotating or translating the stent during a coating process. Leidner et al or Jayaraman lacks teaching the specific configuration of the nozzle assembly and the pumps. It is known in the art to use air assisted atomizing nozzle assembly to apply coating on stents or tubular objects. For instance, Bhat et al teaches the use of air atomizing nozzle to coat a stent (see column 15, example 7).

JP'063 discloses (see Fig 1) a coating apparatus capable of coating stent comprising a nozzle assembly having feed conduit (passage 10) capable of feeding polymer, in fluid communication with a source, a solvent feed conduit (8), in fluid communication with the solvent tank, that is not in fluid communication with the polymer feed conduit and dispenses the solvent, the solvent mixes with the polymer when the polymer and solvent are dispensed out from the nozzle assembly, and an atomizing air conduits (4), in communication with the compressed gas port (9), that is not in fluid communication with the polymer feed conduit and the solvent feed conduit and that uses compressed air from the atomizer to atomize the solvent and polymer that are dispensed out from the nozzle assembly (JP' cited for same reasons described above re claims 4-5 and 7-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a nozzle assembly having atomizer as shown by JP'063 in Leidner or Jayaraman to apply a uniform coating without deteriorating coating efficiency on the stent or substrate. Kropfield discloses a pump that pumps material A from a reservoir capable of holding a polymer and drug mixture; a second pump that pumps a second material (B capable of being solvent) from a second reservoir. It would have been

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obvious to one of ordinary skill in the art at the time the invention was made to include a solvent pump that pumps a solvent from a solvent reservoir; a polymer pump that pumps a polymer from a polymer reservoir in Leidner et al or Jayaraman as modified to continuously supply materials to the coating nozzle as shown by Kropfield indicating the entire spraying assembly on Fig 1.

7. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP2003-211063 in view of Kropfield (US 5,810,254) as applied to claim 1 above, and further in view of Leidner et al (US 6,056,993). JP'063 as modified lacks teaching a substrate support capable of supporting stent. Leidner et al discloses (see Fig 1 and column 5, lines 50-67) a stent mandrel fixture capable of securely supporting a stent during a coating process, wherein the stent mandrel-fixture is further capable of rotating or translating the stent during a coating process. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a mandrel supporting rotating and translating a stent to suitably apply the coating onto the substrate and to completely cover coating on the surface of the substrate.

8. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP2003-211063 in view of Kropfield (US 5,810,254) as applied to claim 1 above, and further in view of Jayaraman (US 2003/0099765). JP'063 as modified lacks teaching a substrate support capable of supporting stent. Jayaraman discloses (see Figs 4 and 6) a stent mandrel fixture capable of securely supporting a stent during a coating process,

wherein the stent mandrel-fixture is further capable of rotating or translating the stent during a coating process. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a mandrel supporting rotating and translating a stent to suitably apply the coating onto the substrate and to completely cover coating on the surface of the substrate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yewebdar T. Tadesse whose telephone number is (571) 272-1238. The examiner can normally be reached on Monday-Friday 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Lewin R.F.", is located at the bottom of the page.